IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF MASSACHUSETTS		IN CLERKS OFFICE
		2005 OCT -7 P 2: 40
VISION BIOSYSTEMS (USA) TRADING INC.,)))	U.S. DISTRICT COURT DISTRICT OF MASS.
Plaintiff,	,)	
v.) Civil Action No. 03-CV	7-10391-GAO
VENTANA MEDICAL SYSTEMS, INC.,))	
Defendant.	,))	
VENTANA MEDICAL SYSTEMS, INC.,)))	
Plaintiff,)	
v.) Civil Action No. 05-CV	7-10614-GAO
VISION BIOSYSTEMS INC.,	,))	
Defendant.	,))	

PLAINTIFF'S MEMORANDUM IN SUPPORT OF ITS MOTION FOR SUMMARY JUDGMENT OF NONFRINGEMENT BASED ON COLLATERAL ESTOPPEL

Plaintiff Vision Biosystems Inc. formerly known as Vision Biosystems (USA) Trading Inc. ("Vision") respectfully submits this memorandum, the accompanying Declarations of Ross Barrow and Richard Wydeven, and its Statement of Undisputed Facts in support of its motion for summary judgment of noninfringement of U.S. Patent No. 6,352,861 (the "861 patent") owned by defendant, Ventana Medical Systems, Inc. ("Ventana").

I. NATURE OF THE CASE

In this consolidated action, Ventana alleges that Vision has infringed and induced infringement of its '861 patent by importing, using, selling and offering to sell versions of its BondTM automated slide-staining instruments using either bar codes or optical character recognition ("OCR") to identify slides.

This motion is dispositive of both of the cases consolidated into the present action. It is based on a recent decision of the United States District Court for the District of Arizona and the deference that this Court accords to final judgments of other U.S. district courts under principles of collateral estoppel and issue preclusion. The infringement issue involves two questions:

- (1) what is the proper construction of the asserted claims of the '861 patent; and
- does Vision's BondTM System fall within those claims, as properly construed. (2)

The first question is purely one of law, and it has already been answered. The Arizona Court has construed the claims at issue in such a way that they cannot be infringed by the use of any embodiment of Vision's instruments that has been commercialized in the United States. Ventana Medical Systems, Inc. v. BioGenex Laboratories Inc., No. 03-92 (D. Ariz, Aug. 23, 2005) (copy of slip opinion attached as Exhibit 1 to the Declaration of Richard Wydeven). The Arizona court has interpreted the "dispensing" limitation in the claims to mean "direct dispensing." The Arizona court has also held that prosecution history estoppel "further narrows the construction of the term 'dispensing' by excluding 'sip and spit dispensing' from its meaning." Ventana v. BioGenex, No. 03-92, slip op. at 16. The Arizona court's claim construction has now been incorporated into a final and appealable judgment pursuant to stipulation of the parties. Wydeven Dec. Ex. 3. Ventana is bound under principles of collateral estoppel and issue preclusion by the Arizona court's decision.

The second question is a factual inquiry about which there is no genuine dispute. Vision's Bond™ System, like that involved in the <u>Ventana v. BioGenex</u> case, employs "sip and spit" dispensing, not "direct dispensing" as required by the '861 patent claims. Therefore, Vision is entitled to judgment of noninfringement as a matter of law.¹

II. STATEMENT OF FACTS

A. The '861 Patent

Ventana has represented that it is the owner of the '861 patent, which claims automated slide-staining apparatus and methodology. The only claims asserted against Vision are method claims 1, 2², 3, 5, 7 and 8. Each of these claims include the step of "dispensing" reagent from a reagent container onto a slide. A copy of the '861 patent is attached as Exhibit 2 to the Wydeven Declaration.

B. Vision's BondTM System

The bar code and OCR versions of the Vision Bond[™] System use identical means for applying reagents to the slides. In neither of them is reagent dispensed directly from a reagent container onto a slide. In those instruments, with regard to staining reagents, (1) a robotic arm moves a pipette to a position above the reagent container; (2) the pipette aspirates reagent from the reagent container; (3) the robotic arm moves the aspirated reagent from a position above the reagent

On September 30, 2004, this Court granted Ventana's motion for summary judgment of infringement based on its interpretation of claim terms different from the one addressed by the Arizona court. Vision does not challenge this Court's earlier claim construction in this motion, but in view of the Arizona court's construction of "dispensing" and the judgment of noninfringement pursuant to this motion, Vision respectfully moves this Court to modify its September 30, 2004 order and vacate its earlier finding of infringement in favor of Ventana.

Ventana is not asserting claim 2 against Vision's bar code system.

container to a position above the slide³; and (4) the pipette releases the reagent onto the slide. Barrow Dec. ¶¶ 2-6, 8-10.

In the Vision BondTM System, so-called "bulk reagents" also are applied to the slides by a sip-and-spit method very similar to that used to apply the staining reagents. Bulk reagent is aspirated from the appropriate reagent container into an electromechanically activated syringe. This is the "sip" step. Bulk reagent is then expelled from the syringe through tubing to the same pipette on the robotic arm that is used for applying staining reagents. The pipette is positioned over the appropriate slide, and bulk reagent is expelled onto the slide. This is the "spit step." Barrow Dec. ¶ 7.

The Vision BondTM System employs the same type of dispensing that the Arizona court denominated "sip and spit" dispensing. Therefore, manufacture, use, sale, importation, and offer for sale of Vision's BondTM System does not infringe the '861 patent. There can be no dispute about the operation of the Vision BondTM instruments or the manner in which they apply reagents to slides. Ventana's trial counsel and in-house counsel have personally inspected each of the bar code and OCR versions and have seen them in operation. They have also deposed knowledgeable Vision witnesses about their operation pursuant to Fed. R. Civ. P. 30(b)(6).

For some reagents an intermediate mixing step is employed. That step involves first depositing reagents from different reagent containers into a mixing container. The robotic pipette then transfers the resulting mixed reagents to the appropriate slides.

III. ARGUMENT

A. The Claims of Ventana's '861 Patent Have Been Construed by the Arizona Court as a Matter of Law and Ventana Is Bound by This Construction under the Doctrine of Issue Preclusion

To determine if a patent has been infringed, the court must undertake a two-step analysis.

Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1580-81 (Fed. Cir. 1996). First, the claims of the patent must be construed to determine the correct scope of the patentee's right to exclude.

Markman v. Westview Instruments, 517 U.S. 370, 384 (1996). Second, the accused product must be compared to those claims, as properly construed, to determine if every element of the claim is met by the accused infringing device, either literally or under the doctrine of equivalents. Vitronics, 90 F.3d at 1580-81.

1. Claim interpretation: the first step in an infringement analysis

The Arizona court held as a matter of law that "dispensing" means "direct dispensing" in the claims of the '861 patent. Ventana v. BioGenex, No. 03-92, slip. op. at 5-7. The Arizona court explained that "the reagent is directly dispensed (without any intermediate transferring device) from an inverted reagent container onto the slide." Ventana v. BioGenex, No. 03-92, slip op. at 7. The Arizona court rejected Ventana's argument that "dispensing" means "applying the agent." Ventana v. BioGenex, No. 03-92, slip op. at 5-7.

The Arizona court also held as a matter of law that the applicants for the '861 patent had clearly and unmistakably disclaimed "sip and spit" dispensing during prosecution. <u>Ventana v. BioGenex</u>, No. 03-92, slip op. at 8-11. The Arizona court described "sip and spit" dispensing as follows: "[i]n sip and spit dispensing, the reagent container and sample slide(s) are side-by-side. Some transport mechanism (i.e. micropipette or probe, essentially a straw-like structure) 'sips' the

reagent from the reagent container by suction and then moves over to the slide and 'spits,' or releases, the reagent onto the slide." Ventana v. BioGenex, No. 03-92, slip. op. at 8. The Arizona court rejected Ventana's argument that the prosecution disclaimer did not apply to the '861 patent. Ventana v. BioGenex, No. 03-92, slip op. at 8-11.

2. Ventana is bound by the Arizona court's construction of the '861 patent claims

This Court need not and should not review the merits of the Arizona court's claim construction.

Under the doctrine of issue preclusion, also called collateral estoppel, a judgment on the merits in a first suit precludes re-litigation in a second suit of issues actually litigated and determined in the first suit . . . [A]pplication of issue preclusion centers around whether an issue of law or fact has been previously litigated. The underlying rationale of the doctrine of issue preclusion is that a party that has litigated an issue and lost should be bound by that decision and cannot demand the issue be decided over again.

In re Freeman, 30 F.3d 1459, 1465, (Fed. Cir. 1994) (citations omitted); Pharmacia & Upiohn Company v. Mylan Pharmaceuticals Inc., 170 F.3d 1373, 1379 (Fed. Cir. 1999) ("Collateral estoppel, also known as issue preclusion, shields a defendant from having to litigate issues that have been fully and fairly tried in a previous action and decided adversely to a party.").

Issue preclusion is appropriate where (1) the issue is identical to one decided in the first action; (2) the issue was actually litigated in the first action; (3) resolution of the issue was essential to a final judgment of the first action; and (4) the issue was actually resolved in a valid and final binding judgment. Monarch Life Insurance Co. v. Ropes & Gray, 65 F.3d 973, 978 (1st Cir. 1995)4:

The Federal Circuit has held that "the application of general collateral estoppel principles, such as finality of judgment is not a matter within the exclusive jurisdiction of this court" and that it "must apply the law of the circuit in which the district court" sits. Pharmacia & Upjohn, 170 F.3d at 1381.

Rosenfeld v. Egy, No. 01-10730, 2003 U.S. Dist. LEXIS 1302, at *17-18 (D. Mass. Jan. 29, 2003); Restatement (Second) of Judgments § 29 (1982).

In the context of claim construction, "where a determination of the scope of patent claims was made in a prior case, and the determination was essential to the judgment there on the issue of infringement, there is collateral estoppel in a later case on the scope of such claims." <u>Pfaff v. Wells Electronics. Inc.</u>, 5 F.3d 514, 518 (Fed. Cir. 1993) (quoting <u>Molinaro v. Fannon/Courier Corp.</u>, 745 F.2d 651, 655 (Fed. Cir. 1984)).

Each of the requirements for collateral estoppel is met here. <u>First</u>, the identical legal issue presented here, namely the appropriate construction of the patent claims, was decided in the <u>Ventana v. BioGenex</u> litigation. <u>In re Freeman</u>, 30 F.3d at 1466 ("the identical issue, the interpretation of the phrase, 'buoyant uplift,' presented in the district court litigation is also present in the reexamination proceeding.").

Second, the claim construction issue was actually litigated in the <u>Ventana v. BioGenex</u> litigation. The parties disputed the interpretation of the "dispensing" limitation and whether prosecution history estoppel applied. The Arizona court rejected Ventana's contention that "dispensing" means "applying the agent," and instead adopted BioGenex's contention that it means "directly dispensing." The Arizona court also rejected Ventana's argument that the prosecution disclaimer did not apply to the '861 patent, and instead agreed with BioGenex that the applicants for the '861 patent had clearly and unmistakably disclaimed during prosecution any interpretation of the claims that could include "sip and spit" dispensing. "Therefore, it is clear that the issue – the meaning of [dispensing] – was actually decided." In re Freeman, 30 F.3d at 1466.

Third, resolution of the claim construction issue was essential to the final judgment in the Ventana v. BioGenex case, as made clear in the Arizona court's judgment:

- A. The accused products in this litigation do not perform 'direct dispensing' as that term is used in the Court's Order and Opinion on Motion (Aug. 29, 2005) (Docket No. 234) ('Markman Order'). The accused products dispense reagent by means of 'sip and spit dispensing' as that term is used in the Court's Markman Order.
- B. The Court's construction of the term 'dispensing' in the Markman Order precludes a finding of infringement of claims 1, 2, 3, 5, 6 and 8 of the '861 patent. The accused products do not infringe claims 1, 2, 3, 5, 6 and 8 of the '861 patent by virtue of findings 1 and 2 of the Court's Markman Order and by virtue of the fact that the accused products do not practice 'direct dispensing.'

Wydeven Dec. Ex. 3, Final Judgment of Noninfringement at 1. The "interpretation of the phrase [dispensing] was the reason for [Ventana's] loss on the issue of infringement . . . Thus, the interpretation of the phrase [dispensing] was necessary to the district court's judgment." See In re Freeman, 30 F.3d at 1467.

<u>Finally</u>, there is "no reason to doubt the quality, extensiveness, or fairness of the procedures followed in the [Arizona] district court." <u>In re Freeman</u>, 30 F.3d at 1467. Therefore, the issue of claim construction was actually resolved in a valid and final binding judgment of noninfringement. Accordingly, principles of issue preclusion bar Ventana from re-litigating the claim construction issue.

- B. Vision Is Entitled to Judgment as a Matter of Law That Its BondTM System Does Not Infringe Ventana's '861 Patent
 - 1. Summary judgment is appropriate for this case

The Supreme Court has encouraged the use of summary judgment to resolve disputes and to simplify issues.

Summary judgment procedure is properly regarded not as a disfavored procedural shortcut, but rather as an integral part of the Federal Rules as a whole, which are designed 'to secure the just, speedy and inexpensive determination of every action.'

Celotex Corp. v. Catrett, 477 U.S. 317, 327 (1986) (quoting Fed. R. Civ. P. 1) (citation omitted).

The Federal Circuit has similarly recognized the benefits of summary judgment in patent cases.

Summary judgment is as appropriate in a patent case as in any other. Where no genuine issue of material fact remains and the movant is entitled to judgment as a matter of law, the Court should utilize the salutary procedure of Fed. R. Civ. P. 56 to avoid unnecessary expense to the parties and wasteful utilization of the jury process and judicial resources.

Barmag Barmer Machinenefabrik AG v. Murata Machinery, Ltd., 731 F.2d 831, 835 (Fed. Cir. 1984).

A factual dispute is genuine only "if the evidence is such that a reasonable jury can return a verdict for the non-moving party." Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 248 (1986). Thus, when the moving party makes a prima facie case,

a non-movant must do more than merely raise some doubt as to the existence of a fact; evidence must be forthcoming from the non-movant which would be sufficient to require submission to the jury of the dispute over the fact.

Avia Group International, Inc. v. LA Gear California, Inc., 853 F.2d 1557, 1560 (Fed. Cir. 1988).

2. Vision's BondTM system does not infringe the '861 Patent

Ventana has the burden of proving infringement by a preponderance of the evidence. Warner-Lambert Co. v. Schwartz Pharma, Inc., 418 F.3d 1326, 1342 (Fed. Cir. 2005). Dispensing is an essential limitation of each of the asserted claims of the '861 patent. Moreover, as properly construed, the claims require direct dispensing. Ventana has the burden of proving that Vision's BondTM System employs direct dispensing. Ventana cannot meet this burden.

The Vision BondTM System (1) aspirates reagent from the reagent container; (2) moves the pipette containing the aspirated reagent to a position above the slide; and (3) applies the reagent to the slide. Barrow Dec. ¶¶ 2-10. In other words, in the Vision BondTM System "reagent is [not] directly dispensed (without any intermediate transferring device) from an inverted reagent container onto the slide." Ventana v. BioGenex, No. 03-92, slip op. at 7. Instead, the Vision BondTM System employs "sip and spit" dispensing - "the reagent container and sample slide(s) are side-by-side. Some transport mechanism (i.e. micropipette or probe, essentially a straw-like structure) 'sips' the reagent form the reagent container by suction and then moves over to the slide and 'spits,' or releases, the reagent onto the slide." Ventana v. BioGenex, No. 03-92, slip op. at 8. The Arizona court rejected Ventana's claim construction argument and decided as a matter of law that dispensing does not include the sip and spit dispensing that is employed in Vision's BondTM System. Ventana v. BioGenex, No. 03-92, slip op. at 8-11. Accordingly, Ventana cannot defeat Vision's motion for summary judgment by arguing that there are genuine issues of material fact that preclude summary judgment.5

C. Summary Judgment Is Appropriate Notwithstanding Ventana's Appeal of the Arizona Court's Judgment

The appropriateness of summary judgment in this case is not diminished by the fact that Ventana intends to appeal the Arizona court's judgment. Collateral estoppel applies "even where

In the alternative, this Court can grant Vision Systems' motion because prosecution history estoppel is also subject to principles of collateral estoppel. International Environmental Dynamics, Inc. v. Fraser, 647 F.2d 77, 78-79 (9th Cir. 1981): 6 Donald S. Chisum. Chisum on Patents §19.02[2][f][iii] (2003). In other words, Ventana is bound by the Arizona court's determination that Ventana clearly and unmistakably disclaimed "sip and spit" dispensing in order to obtain issuance of the '861 patent and is therefore estopped from arguing that an apparatus or system that includes this type of dispensing infringes that patent.

the first, or issue preclusive, judgment is still on appeal when the second action occurs." In re Kane, 254 F.3d 325, 328 (1st Cir. 2001). "First Circuit law [deems] a judgment to be sufficiently 'final' for preclusion purposes even while under appeal." Okor v. Atari Games Corp., Nos. 00-11503, 00-11505, 01-10610, 2002 U.S. Dist. LEXIS 7809, at *25 (D. Mass. Mar. 26, 2002). Entry of summary judgment does not prejudice to the patent owner, because the judgment can be vacated if the predicate judgment is later overturned. Pharmacia & Upjohn, 170 F.3d at 1382 (affirming entry of summary judgment based on collateral estoppel and rejecting the patentee's argument that the case should have been stayed pending appeal of the earlier judgment).

The prompt entry of summary judgment in this case will conserve judicial resources. It will permit consideration by the Federal Circuit of all claim construction issues, including those involved in this Court's earlier claim construction rulings, before the Court or the parties invest resources into further discovery and trial.

IV. CONCLUSION

For the foregoing reasons, Vision respectfully requests that this Court enter summary judgment that Vision's manufacture, use, sale, importation and offer for sale of the Bond™ System does not infringe any claim of Ventana's '861 patent.

Dated: October 6, 2005

Respectfully submitted,

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